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Guidance for the Reregistration of Manufacturing Use and Certain End Use Pesticide Products Containing Dioxathion as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING USE AND CERTAIN END USE PESTICIDE PRODUCTS CONTAINING

DIOXATHION

AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

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This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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I. INTRODUCTION

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth the requirements for registration and reregistration of all manufacturing use products (MUPs) containing the subject chemical as the sole active ingredient. These requirements are: that certain scientific data be submitted; that certain standards of toxicity, composition, labeling, and packaging be met; and that the data compensation provisions of FIFRA Section 3(c)(1)(D) be satisfied. Registrants of MUPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements and compensation responsibilities for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e. registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, IV and VI and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

II REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (the Agency) on registered manufacturing-use products (MUPs) containing the insecticide and acaricide dioxathion. The Agency's position is based on an evaluation of all registered uses and registered MUPs with dioxathion as the sole active ingredient. This position is based on a number of considerations. Foremost among these is an analysis of dioxathion based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Standard also considers labeling requirements, tolerances, "Special Local Needs" registrations authorized by Section 24(c) of the FIFRA, as well as Federal registrations granted or pending under Section 3 of the FIFRA. Finally, the Agency sets forth the data requirements that must be met to register products covered by this document.

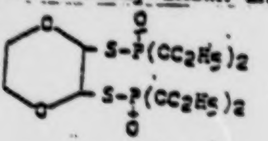
This standard only addresses registration requirements for current or substantially similar future MUPs and their intermediaries. Dioxathion MUPs that differ appreciably from those described here may require amendments to the Standard. End-use products (EUPs) will be registered under the Label Improvement Program.

B. CHEMICAL DESCRIPTION AND USE PROFILE

Dioxathion is the common name established by the American National Standard Institute for both the cis and trans isomers of a compound with the following chemical names: S,S'-p-dioxane-2,3-diyl O,O diethy phosphorodithioate; Phosphorodithioic acid S,S'-1,4-dioxane-2,3-diyl O,O,O',O'-tetraethyl ester; 2,3-p-dioxanedithiol S,S'-bis(O,O-diethyl phosphorodithioate); S,S'-p-dioxane-2,3-diyl O,O,O',O',-tetraethyl phosphorodithioate p-dioxane-2,3-diyl ethyl phosphorodithioate; S,S'-1,4-dioxane-2,3-ylene bis(O,O-diethyl phosphorodithioate).

A manufacturing-use product containing 70% dioxathion is marketed under the trade name Delnav®. The most recent information obtained from BFC Chemicals, Inc. indicates that the typical technical dioxathion is of 73% purity. The remaining 27% is composed of compounds chemically related to dioxathion and impurities. The registrant has been able to identify all but approximately 7-8% of the related compounds and impurities. Current product chemistry data requirements specify certification of upper and lower limits of impurities to within 0.1%. Registrants have the option of complying with this requirement or of providing a rationale as to the reason this requirement cannot be met.

Additional names used for dioxathion include: Compound 528, Hercules AC528, Clertic, Deltic®, ENT-22897, CoNav, DelTox®, and Delspray. The Chemical Abstracts Service (CAS) number is 78-34-2 and the EPA Chemical Reference Number is 037801. The molecular formula is $C_{12}H_{26}O_6P_2S_4$ and the molecular weight is 456.54. The structural formula, which cannot be clearly shown in a two-dimensional figure, is approximately the following:



Dioxathion is an insecticide and acaricide which is federally registered for use on citrus, walnuts, pome and stone fruits, grapes, livestock (including beef cattle, goats, sheep, swine, horses), dogs and their quarters, ornamentals (outdoor), domestic dwellings, recreational areas and commercial establishments (outdoor). Dioxathion is primarily used to control mites on citrus and walnuts; horn flies and lice on beef cattle; and hog louse on swine.

Technical dioxathion is a tan to dark yellow liquid and is relatively unstable thermally. The trans stable isomer begins to decompose at 130°-140°C.

As of February, 1983 Hercules Chemical Company is the sole manufacturer of technical dioxathion in the United States. All of the technical dioxathion manufactured is purchased by BFC Chemical, Inc. who then markets the manufacturing-use material to pesticide formulators.

Dioxathion and related compounds are formulated into the following emulsifiable concentrates: 2.57, 4, and 8 lb/gal and 5, 15, 16.9, 25, 26, 27.5, 29.4, 30, and 47% concentrate. Dioxathion is also formulated with the following other active ingredients: chlorobenzilate, diethyl diphenyl dichlorethane and related products, dichlorvos, and malathion. There are 19 federally registered end-use products containing dioxathion as their sole active ingredient and 8 end-use products which contain dioxathion plus other active ingredients.

Dioxathion is applied to the foliage of agricultural crops with ground equipment and to a lesser extent with aerial equipment. When used on livestock, dioxathion is applied directly to the animal with hydraulic sprayers. Most dioxathion formulated products are classified as restricted use pesticides and, therefore, must be applied by certified applicators or by applicators under their direct supervision.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on dioxathion, the Agency has made the following determinations:

1. Manufacturing-use pesticide products containing dioxathion as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this standard.

2. Available data do not show that any of the criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded by the uses of dioxathion specified in this standard. However, gaps in the data base preclude the completion of the Agency's risk assessment.

3: The "Restricted Use" classifications for the following dioxathion use patterns will continue: all uses of solutions and emulsifiable concentrates containing more than 30% dioxathion; domestic uses of concentrate solutions or emulsifiable concentrates containing 30% and less dioxathion and wettable powders containing 25% and less dioxathion; and domestic uses of solutions containing 3% or greater dioxathion. The results of the acute dermal toxicity tests provided the basis for the decision to designate certain use patterns of dioxathion as restricted, unclassified, or under evaluation. This decision was published in the Federal Register, Vol. 44, August 1, 1979. These use classifications will remain in effect but will be reviewed when the data required to fill toxicological data gaps for dioxathion under this standard have been received and evaluated.

4. Registrants must provide or agree to develop additional data, as specified in the tables attached to this standard, in order to maintain existing registrations or to permit new dioxathion registrations.

5. Tolerance reassessment is normally a part of a Registration Standard review. The Agency is unable to complete its reassessment of dioxathion tolerances because necessary toxicology and residue data are not available. Additionally, pesticide registrants should petition the Agency to establish a tolerance for dioxathion in apple pomace (21 CFR 561.210). Even though the Theoretical Maximum Residue Concentration (TMRC) of dioxathion in the daily diet exceeds the Maximum Permissable Intake (MPI), the Agency has no evidence to indicate that current tolerances will result in residue levels that will expose the public to unreasonable adverse effects.

D. REGULATORY RATIONALE

The Agency has determined that it should continue to allow the registration of dioxathion after considering the following:

1. Acute toxicity data indicate that technical dioxathion has a high acute oral toxicity (Toxicity Category I) as well as a high acute dermal toxicity (Toxicity Category I) (00005467). Acute intoxication symptoms include depression, salivation, lacrimation, rapid and labored respiration, tremors, and clonic convulsions. Rat and mouse inhalation studies indicate that technical dioxathion is moderately toxic (Toxicity Category II). No data are available to assess the primary eye and skin irritation or skin sensitization potential of technical dioxathion. A study using Osborne-Mendel rats and B6C2F1 mice was conducted to assess the carcinogenic potential of technical grade dioxathion. The results of this study indicate dioxathion is not carcinogenic in these strains of rats and mice when administered in the diet. No data are available to assess the reproductive, teratogenic, or mutagenic effects of dioxathion.

2. Available data are insufficient to fully assess the environmental fate of dioxathion or to assess the potential exposure of humans and non-target organisms to dioxathion.

3. Dioxathion has a high acute oral and dermal toxicity. Therefore, potential hazards to farmworkers posed by dioxathion residues in the agricultural workplace are of concern to the Agency. The Department of Food and Agriculture for the State of California has established a safe reentry interval for dioxathion of 30 days for citrus, peaches, nectarines, and grapes. For all other crops, a 24-hour safety interval exists which applies after application of a Toxicity Category I pesticide. A federal reentry interval has not been established. Registrants may either accept the reentry intervals proposed by the California Department of Food and Agriculture or submit data and propose acceptable reentry intervals for each agricultural crop.

4. Ecological effects data are available to assess the toxicity of dioxathion to several terrestrial and aquatic test organisms. Dioxathion is characterized as slightly toxic to birds, very highly toxic to both coldwater and warmwater fish, and highly to very highly toxic to freshwater aquatic invertebrates. Since some of the acreage treated with dioxathion is in close proximity to aquatic environments, there is an opportunity for freshwater and estuarine fish and invertebrates to be exposed via runoff, drift, or inadvertent direct application. Thus, the potential exists for aquatic species to be adversely affected by the use of dioxathion. Label precautionary statements required by this Standard should reduce the hazard to aquatic species. Dioxathion has been shown to be relatively non-toxic to honey bees.

5. Residue metabolism studies show residues of the technical chemical in both plants and animals to consist of dioxathion per se together with the diethyl esters of phosphoric, phosphorothioic and phosphorodithioic acid, and the salts of these acids. The residue of toxicological interest is dioxathion per se. Adequate methods of determining residues of dioxathion in various commodities exist and residue studies have been submitted indicating the magnitude of dioxathion residue from applications to both crops and livestock. Data are needed on some of the processed food products of the various crops treated with dioxathion. These data are specified in Table A of this Standard.

6. Dioxathion has been registered for use since May 28, 1957. The Pesticide Incident Monitoring System (PIMS) records for the period July, 1978 to August, 1981 include 15 incidents involving dioxathion. Twelve of these incidents involved humans and three involved animals. One human incident resulted in a fatality but the incident also involved exposure to other pesticides in addition to dioxathion, the route of exposure was not reported, and the person was not a certified pesticide applicator.

7. In accordance with FIFRA, the Agency cannot routinely cancel existing registrations of products or withhold registration merely for lack of data unless risks are clearly identified from the data that have been submitted and evaluated. Rather, the publication of this Standard provides a mechanism for identifying data needs. Registration of dioxathion under this Standard will allow for the upgrading of labels during the period in which the required data are being generated.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

All manufacturing-use products which contain dioxathion as the sole active ingredient are subject to this standard and must either comply with the acute toxicity limits, product composition, and use pattern requirements listed in Section F of this document or submit data and a justification to amend the standard to encompass such products.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it, including a commitment to fill data gaps on a schedule specified by the Agency. Applicants must also indicate a willingness to pay compensation for data to the extent required by Section 3(c)(1)(D) of the FIFRA, as amended, 7 U.S.C. 136(c)(1)(D). Applicants for registration under this standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standards

To be covered under this standard, manufacturing-use products must contain at least 69% dioxathion as the sole active ingredient. The composition of each manufacturing-use dioxathion product must be substantially similar to that in currently registered manufacturing-use products. Any manufacturing-use product not meeting these requirements will be considered a new product and will require an amendment to the standard.

2. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use products containing dioxathion for any acute toxicity category, provided that the labeling of those products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing dioxathion may be labeled for formulation only into end-use products for:

a. Terrestrial, Non-Domestic, Food Uses

pome fruits - (apples, pear, quince)
stone fruits - (apricot, cherry, peach, plum, prune)
citrus - (grapefruit, orange, tangelo, tangerine, lemon, lime)
grapes
walnuts
beef cattle, goats, sheep, swine, horses

b. Terrestrial, Non-Domestic, Non-Food Uses

horses - (not intended for slaughter)
ornamentals
recreational areas
commercial, institutional, and industrial areas

c. Indoor/Outdoor, Non-Domestic Uses

dogs and their living quarters
domestic dwellings

End-use products formulated from products registered under this standard may be concentrate solutions or emulsifiable concentrates.

G. REQUIRED LABELING

All manufacturing-use and end-use products containing dioxathion must bear appropriate labeling as specified in 40 CFR 162.10. Additionally, some backrubber dioxathion solution labels recommend solvents which have not been cleared for application to animals under 40 CFR 180.1001(e) (e.g.; diesel oil, fuel oil, light motor oil). Under the Label Improvement Program, the labeling of backrubber products must be revised to recommend only approved solvents.

1. Use Pattern Statements

All dioxathion manufacturing-use products must contain one or more of the following use pattern statements listed below:

- Terrestrial, Non-Domestic, Food Use on [specify food crops]
- Terrestrial, Non-Domestic, Non-Food Use on [specify non-food sites]
- Indoor/Outdoor, Non-Domestic Use on [specify sites]

2. Precautionary Statements

Labels for all manufacturing-use products containing dioxathion must bear statements reflecting the acute human toxicity of the compound. The guidance package provides an updated list of all precautionary statements which must appear for each type of product.

The following environmental hazard warning statement must appear on all manufacturing-use product labels:

> "This product is toxic to fish. Do not discharge into lakes, streams, ponds, or public water unless in accordance with an NPDES permit. For guidance, contact your Regional Office of EPA."

Label changes to EUP's are not required by this standard. However, based on data reviewed by the Agency, the following environmental statements will be called for when EUP's are reregistered under the Agency's Label Improvement Program.

End-use products intended for application to crops will have the following statement on labels:

> "This pesticide is toxic to fish. Do not apply directly to water or wetlands. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

End-products intended for application to domestic animals will have the following statement on the labels:

> "Do not contaminate water by cleaning of equipment or disposal of wastes."

The Agency may impose additional label requirements after the receipt and review of the data to be submitted under this standard.

H. TOLERANCE REASSESSMENT

A summary of tolerances for dioxathion is presented in Table I. This table also includes information on Canadian and Codex tolerances for dioxathion. The tolerances established in the United States were derived from data submitted to the Agency from 1959-1970 and are based on studies conducted with a technical product containing dioxathion (70%) and compounds chemically related to dioxathion (30%).

Additionally, the current required labeling prohibits the feeding of dioxathion-treated apples and apple pomace to meat and dairy animals. This is not the current agricultural practice and the restriction is considered impractical.

The current no effect level (NOEL) of 1.0 ppm is based on the results of an 90-day rat feeding study. Considering the NOEL of 1.0 ppm and a safety factor of 200, the provisional allowable daily intake is 0.00025 mg/kg/day and the Maximum Permissable Intake (MPI) for a 60 kg person is 0.015 mg/day. Based on the existing tolerances, the Theoretical Maximum Residue Concentration (TMRC) of dioxathion for a 60 kg person consuming 1.5 kg/day of food is 0.5498 mg/day.

Pesticide registrants should petition the Agency to establish a tolerance for dioxathion in apple pomace (21 CFR 561.210). Based on residue data available to the Agency, a tolerance of 18 ppm is recommended for apple pomace.

There is a 36:1 ratio between the TMRC and the MPI which means that theoretically the amount of dioxathion in the daily diet exceeds the daily permissable amount. In the initial calculation of the TMRC and the MPI, the following assumptions are made: the residue level of dioxathion in a particular commodity is considered to be at the tolerance level; 100% of the U.S. crop for which a dioxathion tolerance exists is treated with dioxathion; and a Margin of Safety (MOS) value of 200 is used.

These assumptions can result in an overestimation of the TMRC, MPI, and the resulting ratio. The residue level of a pesticide in a given commodity is generally less than the tolerance level and the percent of a crop that is actually treated with a specific pesticide is rarely 100%. Also, the current calculations are based on the results of cholinesterase effects in a subchronic study and, therefore, a MOS of 200 was used. If a chronic study with the similar effect as that observed in the subchronic study were available, the standard practice is to use a MOS of 10.

The following data are needed to allow for a precise definition of the NOEL and to clarify the TMRC, MPI, and the TMRC:MPI ratio: chronic feeding studies in rodent and non-rodent; reproduction study; teratology study in two species; acute delayed neurotoxicity; residue data on processed citrus, grapes, and apple products; percentage of crop treated; and evaluation of actual residues levels versus tolerance levels.

Additionally, these data will be used to determine whether the current tolerance for residues of dioxathion in milk should be raised to conincide with the Codex milk tolerance of 0.2 ppm.

Table 1. Summary of present tolerances for dioxathion

Commodity	Tolerances (ppm)			
	United States	Canada	Mexico[a]	International (Codex)
Apples	5.0	5.0	-	-
Cattle, fat of meat	1.0	1.0	-	-
Dehydrated citrus pulp (for cattle)	18.0	-	-	-
Goats, fat of meat	1.0	1.0	-	-
Grapefruit	3.0	3.0	-	-
Grapes	2.0	2.0	-	-
Hogs, fat of meat	1.0	1.0	-	-
Horses, fat of meat	1.0	-	-	-
Lemons	3.0	3.0	-	-
Limes	3.0	3.0	-	-
Milk	0.0	-	-	0.2
Oranges	3.0	3.0	-	-
Pears	5.0	5.0	-	-
Quinces	5.0	5.0	-	-
Sheep, fat of meat	1.0	1.0	-	-
Stone fruit	0.1	-	-	0.1
Tangerines	3.0	3.0	-	-
Walnuts	0.14[b]	-	-	-

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[a] Mexico has no established tolerances for dioxathion.
[b] Negligible residues

Please refer to cover letter concerning data compensation.

III. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix III-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D).

B. A statement acknowledging that if EPA approves your application for registration, the approval will be based on EPA's consideration of the following:

1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing Use and End Use Products" (Table A at the end of Section IV), is relevant to EPA's evaluation of the registrability of your product.

2. For the manufacturing use products, the "product-specific" data* which you have listed on the form entitled "Product-Specific Data Report" (Appendix III-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

1. Persons to whom offers must be made: An offer must be furnished to each person who was the original submitter of any of the generic or product specific data upon which approval of your application will be based, except that:

a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

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*/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

b. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the bibliography (Appendix III-3) who have not waived their rights to receive offers will be listed in Tables A and B (MUP registrants are referred to both Tables A & B; end-use product registrants are referred to only Table A). You will be required to write the companies listed in the appropriate table(s) if the data in those tables are required to support your formulations and/or uses.

c. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.

d. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.

2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

   a. A notification of your intent to apply for registration or reregistration under this guidance document, and the name, active ingredient, and intended uses of your product.

   b. An offer to pay the person compensation with respect to approval of your application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

   c. Your name, mailing address, and telephone number.

IV. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, The Pesticide Registration Guidelines,*/ or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section V of this document.

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*/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

C. Options Available for Complying with Requirements to Submit Data.

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA § 3(c)(2)(B) Summary Sheet" [Appendix IV-2(a)] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" (Appendix IV-3*/.

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing. (Footnote continued on next page.)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Continued)
As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)], and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

V. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA § 3(c)(2)(B)

Note: This section applies only to manufacturing use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than 6 months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under § 3(c)(2)(B)."

In some cases Table B may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, you must comply with FIFRA Section 3(c)(1)(D). See Section III of this guidance document.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.120 Product Chemistry				
Product Identity:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Partially	GS0089013	Yes[3/]
61-2 - Description of Beginning Material and Manufacturing Process	TGAI	Partially	GS0089013	Yes[4/]
61-3 - Discussion of Formation of Impurities	TGAI	Partially	GS0089013	Yes[3/]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Partially	GS0089013	Yes[3/]
62-2 - Analytical Methods	TGAI	Partially	00077624[11/] 00077580 05002358	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS0089013[11/] GS0089005	No
63-3 - Physical State	TGAI	Yes	GS0089013	No
63-4 - Odor	TGAI	Partially	GS0089005	Yes[5/]
63-5 - Melting Point	TGAI	-	-	No[6/]
63-6 - Boiling Point	TGAI	No	-	Yes
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	10/	No

TABLE A
GENERIC DATA REQUIREMENTS FOR DICKATHION

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	Partially	GS008901311/ 00077624*	Yes7/
63- 9 - Vapor Pressure	TGAI OR PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	No	-	Yes8/
63-13 - Stability	TGAI	Partially	GS0089005	Yes7/
Other Requirements:				
64- 1 - Submittal of samples	TGAI	Partially	-	Yes9/

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient.

2/ Data must be submitted no later than six (6) months.

3/ On the basis of chemical theory, a discussion is needed concerning the ingredients and impurities that are present in technical dioxathion (TGAI). This discussion is expected to consider the data and information on the description of beginning material and manufacturing process and the results of the preliminary analysis which should provide quantitative data for each component of the TGAI which is equal to or greater than 0.1%. If the sum of the individual analyses is much less than ca 98%, the need for additional analyses and further testing will be discusses with the manufacturer.

4/ The submitted description of the beginning materials and manufacturing process is not specific. The information submitted indicates three procedures by which dioxathion can be synthesized. The registrant should identify the beginning materials (with information on their impurities) and provide a flow chart of the basic manufacturing reactions. Information is also needed for the side reactions, reaction temperatures and reaction solvents which significantly effect the composition of the TGAI.

5/ Odor is reported as unpleasant. A more definitive description is required.

6/ Not required for a liquid product.

7/ In order to adequately characterize the chemical/physical properties of dioxathion, data are needed to show the solubility of the technical chemical in common solvents (e.g., chloroform, carbon disulfide) and the effects of potential impurities (e.g., acids, alkali, metallic contaminants) on its stability.

8/ Required if technical dioxathion is sufficiently soluble in water at 25°C to permit a pH determination by the recommended procedures.

9/ Each dioxathion manufacturer may be required to submit a sample of his TGAI if the need arises. Unless the manufacturing process is changed significantly, this submission would occur only at the time of first registration.

10/Data obtained from the Merck Index, 9th Edition, 1976.

11/All of the data cited are needed to satisfy this data requirement.

* STudies submitted by Zoecon Industries Inc. These studies may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes	GS0089017[4] GS0089018 00077581 00077601	No
- Livestock	PAIRA and plant metabolites	Yes	00077645[4] 00077621 00077619 00077624* 00077644 00077601	No
171-4 - Residue Analytical Method				
- Residues in plants	TGAI and metabolites	Yes	00077580	No
- Residues in animals	TGAI and metabolites	Yes	00077580	No

TA[illegible] A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirements	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry				
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use				
- Storage Stability Data	TGAI	Yes	05004877	No
- Citrus				
o Crop field trials (whole fruit)	TEP	Yes	00077579[4/] 00077578	No
o Processed Food/Feed	EP			
o Citrus Pulp (wet and dry)		Yes	00077579	No
o Citrus Molasses		No	-	Yes
o Citrus Oil		No	-	Yes
o Citrus Juice		No	-	Yes
- Grapes				
o Crop field trials (grapes)	TEP	Yes	00077641[4/] 00077623	No
o Processed Food/Feed	EP			
o Grape juice		No	-	Yes
o Grape pomace		No	-	Yes

TA A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirements	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171.4 - Residue Data, Crops				
o Raisins		No	-	Yes
o Raisin wastes		No	-	Yes
- Pome fruit (apples, pears)				
o Crop field trials (whole fruit)	EP	Yes	00077610[4/] 00077609	No
o Processed Food/Feed	EP			
o Apple Pomace		Yes	00077609	No
o Apple juice		No	-	Yes
- Stone Fruit (cherrries, peaches)				
o Crop field trials	TEP	Yes	00077616	No
- Walnuts				
o Crop field trials	TEP	Yes	00077618	No

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Potable Water	EP	No	-	No3/
- Food Handling	EP	No	-	No3/
- Meat/milk/poultry/eggs	TGAI or plant metabolites			
-- Milk		Yes	050046904/ GS0089013	No
— Meat		Yes	000776444/ 00077642	No

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than thirty-six (36) months.

3/ Studies providing residue data in potable water and in or on food/feed are not needed to support currently registered dioxathion products. When products are proposed with direct application to water, data for residues in potable water will be needed unless it can be shown that the treated water will not be used for drinking by man or animals. When products are proposed for use in food/feed handling establishments, data for residues in the items of food/feed will be needed.

4/ All of the data cited are needed to satisfy this data requirement.

* Studies submitted by Zoecon Industries Inc. These studies may be compensable.

TAB

GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No	-	Yes
161-3 - On soil	TGAI or PAIRA	A,B	No	-	Yes
161-4 - In Air	TGAI or PAIRA	A,B	No	-	Yes
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Partially	00043982 *	Yes4/
162-2 - Anaerobic Soil	TGAI or PAIRA	-	-	-	No5/
162-3 - Anaerobic Aquatic	TGAI or PAIRA	-	-	-	No6/
162-4 - Aerobic Aquatic	TGAI or PAIRA	-	-	-	No6/
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	No	-	Yes
163-2 - Volatility (Lab)	TEP	A,B	No	-	Yes
163-3 - Volatility (Field)	TEP	A,B	-	-	Reserved7/

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	No	-	Yes
164-2 - Aquatic (Sediment)	TEP	-	-	-	No6/
164-3 - Forestry	TEP	-	-	-	No6/
164-4 - Combination and Tank Mixes		-	-	-	No8/
164-5 - Soil, Long-term	TEP	-	-	-	No9/
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	-	-	-	No5/
165-2 - Rotational Crops (Field)	TEP	-	-	-	No5/
165-3 - Irrigated Crops	TEP	-	-	-	No10/
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	Yes
165-5 - In Aquatic Non-Target Organisms	TEP	A,B	-	-	Reserved11/

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than thirty-six (36) months.

4/ A study must be made whereby the metabolites are identified and a material balance calculated.

5/ Waived because field/vegetable crop use is negligible.

6/ The current registered uses for dioxathion do not include aquatic or forestry use, consequently, these data are not required.

7/ Reserved, pending results from the laboratory volatility data.

8/ Standard deals only with a single active ingredient.

9/ These data are not required because more than 50% of the dioxathion applied dissipates before another application.

10/ Use pattern does not require this test.

11/ These data are not required because dioxathion does not have any forestry, aquatic noncrop, or aquatic impact uses.

* Studies submitted by Montedison USA, Inc. These studies may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,H,I	Yes	00005467 8/ 00077586	No
81-2 - Dermal LD_{50}	TGAI	A,B,H,I	Yes	00005467 8/ 00077591*	No
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,H,I	Yes	00077561	No
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,H,I	Partially	00077592	Yes 4/
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B,H,I	Yes	00077598 00077597 9/ 00077600	No
82-2 - 21-Day Dermal	TGAI	-	-	-	No 5/
82-3 - 90-Day Dermal	TGAI	-	-	-	No 5/
82-4 - 90-Day Inhalation - Rat	TGAI	-	-	-	No 5/
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI	-	-	-	Reserved 6/

TABLE
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B,H,I	No	-	Yes
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,B,H,I	Yes	GS0089022	No
83-3 - Teratogenicity - 2 species	TGAI	A,B,H,I	No	-	Yes
83-4 - Reproduction, 2-generation	TGAI	A,B,H,I	No	-	Yes
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B,H,I	No	-	Yes
84-2 - Chromosomal Aberration	TGAI	A,B,H,I	No	-	Yes
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,H,I	No	-	Reserved7/

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B,H,I	Yes	00077640 10/ 00077602 05004316	No
85-2 - Domestic Animal Safety	Choice	A,B,H,I	-	-	No

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Acute toxicity data (81-1 through 81-3, 81-7) must be submitted no later than six (6) months. All other data must be submitted no later than thirty-six (36) months.

4/ Additional testing is required to definitely establish if delayed neurotoxicity is present.

5/ Required for formulated product if use pattern results in repeated skin contact (e.g., use on dogs).

6/ Reserved pending results obtained from the acute delayed neurotoxicity data.

7/ Reserved pending results from gene mutation and chromosomal aberration testing.

8/ Either of the studies cited will fulfill this data requirement.

9/ This study satisfies this data requirement.

10/All of the data cited are needed to satisfy this data requirement.

* Studies submitted by Hercules Powder Co. These studies may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/5/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B	No	-	Yes
132-1 - Soil Dissipation	TEP	A,B	No	-	No 4/
133-3 - Dermal Exposure	TEP	A,B	No	-	Yes
133-4 - Inhalation Exposure	TEP	A,B	No	-	Yes

1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later then thirty-six (36) months.

4/ These data are not needed because the use pattern does not involve worker contact with soil.

5/ For each crop, the registrant must propose an acceptable reentry interval; this proposed interval may be based on any of the following: (a) the longest (most restrictive) existing reentry intervals; (b) data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on the inherent toxicity of the chemical; (c) determination of that time beyond which there are no detectable foliar residues (under climatic conditions) in the area where the chemical will be applied. Either the longest (most restrictive) reentry interval is acceptable, or the exposure data and a dislodgeable residue curve, together with the inherent toxicity of the chemical, may be used to establish an appropriate interval for activities that result in foliar contact. The longest (most restrictive) reentry intervals should be listed by crop. A decline curve of foliar residues of dioxathion and metabolites is needed if the registrant does not accept the longest existing reentry interval.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,H	No	-	Yes
71-2 - Avian Dietary LC_{50}	TGAI	A,B,H	Yes	00028757	No
71-3 - Wild Mammal Toxicity	TGAI	-	-	-	No4/
71-4 - Avian Reproduction	TGAI	-	-	-	No4/
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	-	-	-	No4/
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,H	Yes	GS0089001 6/ GS0089002 GS0089003 GS0089004	No
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,H	Yes	GS0089001 7/ 05009242 05017538	No
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A (Citrus)	No	-	Yes
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A (Citrus)	-	-	Reserved5/

TABLE [illegible]
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms (continued)					
72-5 - Fish - Life-Cycle	TGAI	-	-	-	No 4/
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	-	-	-	No 4/
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	-	-	-	No 4/

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than thirty-six (36) months.

4/ The currently registered uses of dioxathion do not require these data.

5/ These data may be required after receipt and review of completed environmental fate data.

6/ Either of the studies (GS0089001, GS0089003) fulfill the freshwater fish LC_{50} data requirement for rainbow trout; either of the studies (GS0089002, GS0089004) fulfill the freshwater fish LC_{50} data requirement in bluegill sunfish.

7/ This study (GS0089001) satisfies this data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirements	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY3/	EP				
NONTARGET AREA PHYTOTOXICITY3/ (122-1 thru 124-2)	TGAI				

1/ Composition: TGAI = Technical grade of the active ingredient; EP = End-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ These data are currently not required to support the continued registration of dioxathion. These data are required on a case-by-case basis to support products for which phytotoxicity problems arise and open literature data are not available; products that may pose hazards to endangered species; or products for which a rebuttable presumption against registration (special review) has been initiated. The Agency reserves the right to require such data for dioxathion in the future should any of the above stated conditions occur.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIOXATHION

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	-	-	-	No
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	-	-	-	No
141-4 - Honey bee subacute feeding study	[Reserved]				
141-5 - Field testing for pollinators	TEP	-	-	-	No

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIOXATHION

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.120 Product Chemistry				
Product Identity				
61-1 - Product Identity and Disclosure of Ingredients	MP	Partially	GS0089013[11/] GS0089021 GS0089006 10/	Yes[3/]
61-2 - Description of Beginning Material and Manufacturing Process	MP	Partially	GS0089013[11/] GS0089006*	Yes[4/]
61-3 - Discussion of Formation of Impurities	MP	Partially	GS0089013	Yes[3/]
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	No		Yes
62-2 - Certification of Limits	MP			
- dioxathion (both isomers)		No	-	Yes
- related compounds and impurities > ca 0.1%		No	-	Yes
62-3 - Analytical Methods for Enforcement of Limits	MP	Partially	GS0089013[11/] 00077624 00077580 05002358	Yes[5/]

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIOXATHION

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
Physical and Chemical Characteristics				
63-2 - Color	MP	No	-	Yes
63-3 - Physical state	MP	Yes	[6]	No
63-4 - Odor	MP	No	-	Yes
63-7 - Density, bulk density, or specific gravity	MP	Yes	[6]	No
63-12 - pH	MP	No	-	Yes[8]
63-14 - Oxidizing or reducing action	MP	No	-	Yes
63-15 - Flammability	MP	Yes	[6]	No
63-16 - Explodability	MP	No	-	Yes
63-17 - Storage Stability	MP	No	-	Yes
63-18 - Viscosity	MP	No[7]	-	Yes
63-19 - Miscibility	MP	No[7]	-	Yes
63-20 - Corrosion Characteristics	MP	No	-	Yes
Other Requirements				
64-1 - Submittal of Samples	MP	Yes[9]	-	No

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than six (6) months.
3/ Currently, dioxathion is being manufactured by only one company (BFC Chemicals, Inc.) and only one manufacturing-use
product of dioxathion is registered. However, the requirements listed in this table apply both to manufacturing-use
products and to those end-use products of dioxathion produced by an integrated-formulation system.
4/ More exact composition data determined by specific and modern procedures are needed concerning the related compounds
and impurities (ca 30%) that are present in technical dioxathion. On the basis of chemical theory, a discussion is
needed concerning the ingredients and impurities that are present in technical dioxathion (TGAI). This discussion
is expected to consider the data and information on the description of beginning materials and manufacturing process
and the results of the preliminary analysis which should provide quantitative data for each component of the
TGAI which is equal to or greater than 0.1%. When the sum of the individual analyses is much less than ca 98%,
the need for additional analyses and further testing will be discussed with the manufacturer.
5/ With the initial petition for the use of dioxathion on citrus, the Agency received an analytical procedure for
determining dioxathion residues in food (MRID 00077580). While it appears that this procedure may be adaptable to the
determination of dioxathion in both the technical chemical (TGAI) and registered products of dioxathion, suitable
methodology for making such determinations should be developed and submitted. Specific composition data, determined
by this methodology, is then needed for the dioxathion (each isomer) in each integrated-formulation product. By any
appropriate methodology, composition data are also needed for the related compounds of dioxathion and the impurities
(>ca 0.1%) which are present in these products.
6/ Included in the Confidential Statements of Formula for the BFC Chemicals, Inc. products.
7/ Not applicable for a solid material.
8/ Data for pH are required for those products sufficiently soluble in water at 25°C to permit a determination by
recommended procedures [see guidelines].
9/ Each dioxathion manufacturer may be required to submit a sample of his TGAI if the need arises. Unless the
manufacturing process is changed significantly, this submission would occur only at the time of first registration.
10/Data also obtained from the Merck Index, 9th Edition, 1976 and Acceptable Common Names and Chemical Names for the
Ingredients on Pesticide Labels. Fourth Edition. EPA-54019.
11/All of the data cited are needed to satisfy this data requirement.

* Studies submitted by BFC Chemicals Inc. These studies may be compensable.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIOXATHION

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00005467 3/ 00077586	No
81-2 - Dermal LD_{50}	MP	Yes	00005467 3/ 00077591*	No
81-3 - Inhalation LC_{50} - Rat	MP	Yes	00077561	No
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes
81-5 - Primary Dermal Irritation	MP	No	-	Yes
81-6 - Dermal Sensitization	MP	No	-	Yes

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than six (6) months.
3/ Either of the studies cited fulfills this data requirement.

* Studies submitted by Hercules Powder Co. These studies may be compensable.

VI. LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you must submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.1], as indicated by the following paragraphs of this section of the guidance document. The labeling must be submitted within 6 months of your receipt of this guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel the registration under FIFRA § 6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix VI-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix VI-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix VI-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net content must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix VI-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix VI-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix VI-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix VI-1. [40 CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word As Required Minimum Type Size All Capitals	"Keep out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix VI-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity Category I on the basis of oral, inhalation or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix VI-1. (40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statement" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix VI-1. [40 CFR §162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix VI-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8 (c)(13)(ii) of Subpart D.

c. A "non-flammable aerosol" is one which meets the following criteria:

   i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii).

   ii. There is no flash back; and

   iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Appendix VI-1 [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix VI-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix VI-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VII. Instructions for Submission

All applications prepared in response to this Notice should be addressed as follows:

[Product Manager] George T. LaPocca
Phone No. (703) 557-2400
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document you must submit the "FIFRA Section (3)(c)(2)(B) Summary Sheet." Refer to Appendix IV-2(a) with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. "Application for Amended Pesticide Registration" (EPA Form 8570-1).

   b. "Confidential Statement of Formula" (EPA Form 8570-4).

   c. "Data Compensation Statement: Reregistration." Refer to Appendix III-1(a).

   d. Product Specific Data Report (Appendix III-2).

   e. Two copies of any required product-specific data.

   f. Two copies of draft labeling, including the label and associated brochures. If the current labeling conforms to the requirements of this guidance document and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either type-written text on 8-1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrants.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit:

1. The "FIFRA Section 3 (c)(2)(B) Summary Sheet" (Appendix IV-2) with appropriate attachments, and

2. The "Data Compensation Statement: Reregistration." Refer to Appendix III-1(b).

Appendix III-1(a)

DATA COMPENSATION STATEMENT: REREGISTRATION (MUPs)

EPA Reg. No.:____

Product Name:____

Applicant's Name & Address: ______________________________
____
____
____

Date of application for reregistration: ____________________

Registration Standard for products containing: ______________

Date Reregistration Guidance Document Issued:________________

In connection with applicant's application for reregistration under the Guidance Document identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Guidance Document identified above, were found relevant to EPA's evaluation of the registrability of applicant's product; and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application; and

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Document identified above.

Dated:____________________________

Name of registrant's
authorized representative: ______________________________
(signature)

____
(typed)

DATA COMPENSATION STATEMENT: REREGISTRATION (End-Use Products)

EPA Reg. No.:____________________________________

Product Name:____________________________________

Applicant's Name & Address: __________________________
____
____

Date of application for reregistration: __________________

Registration Standard for products containing: ____________

Date registration Guidance Document Issued:_______________

Registrant offers to pay compensation to other persons for the data listed in Table A to the extent required by sections 3(c)(1)(D) and 3 (c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registrant has furnished offers to pay compensation to the persons identified in Table A and in the form specified by the Guidance Document.

Dated:________________________

Name of registrant's
authorized representative: __________________________
(signature)

____
(typed)

APPENDIX III-

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._________ Guidance Document for______________________________

Date:____________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with Data Requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID #	Submitting Data (attached)	
163.61-3	Product identity and disclosure of ingredients				
-4	Description of manufacturing process				
-5	Discussion on formation of unintentional ingredients				
-6	Declaration and certification of ingredient limits				
-7	Product analytical methods and data				
163.61-8(1)	Color				
-8(2)	Odor				
-8(3)	Melting Point				
-8(4)	Solubility				
-8(5)	Stability				
-8(6)	Octanol/water partition coefficient				
-8(7)	Physical state				
-8(8)	Density or specific gravity				
-8(9)	Boiling point				
-8(10)	Vapor pressure				
-8(11)	pH				
-8(12)	Storage stability				
-8(13)	Flammability				
-8(14)	Oxidizing or reducing action				
-8(15)	Explosiveness				
-8(16)	Miscibility				
-8(17)	Viscosity				
-8(18)	Corrosion characteristics				
-8(19)	Dielectric breakdown voltage				
163.71-5(1)	Cage or pen field test				
-5(2)	Full scale field test				
163.72-1	Fish acute LC_{50} rainbow trout and bluegill				
163.72-2	Acute toxicity to aquatic invertebrates				
-3	Acute toxicity to estuarine and marine organisms				
-6(a)(1)	Short term simulated field test				
-6(a)(2)	Long term simulated field test				
163.81-1	Acute oral toxicity				
-2	Acute dermal toxicity				
-3	Acute inhalation toxicity				
-4	Primary eye irritation				
-5	Primary dermal irritation				
-6	Dermal sensitization				

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier", or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standardq Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard

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00077580 Dunn, C.L. (1958) Determination of 2,3-p-dioxanedithiol S,S-bis (0,0-diethyl) phosphorodithioate). Journal of Agricultural and Food Chemistry 6(3):203-209. (Also in unpublished submission received May 14, 1959 under PP0202; submitted by Hercules Powder Co., Inc., Wilmington, Del.; CDL:090229-E).

00077602 Dunn, C.L. (1958) Progress Report: Delnav® Development: RI 4658. (Unpublished study received December 14, 1958 under PP0202; submitted by Hercules Powder Co., Wilmington, Del.; CDL:090230-U).

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00005467 Gaines, T.B. (1960) The Acute Toxicity of Pesticides to Rats. Toxicology and Applied Pharmacology 2(1):88-89. (Also in unpublished submission received Feb. 14, 1961 under PP0299; submitted by Chemagro Corp., Kansas City, Mo.; CDL:090320-Q).

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Appendix IV-2(a)

FIFRA §3(C)(2)(B) SUMMARY SHEET

EPA Registration No.:______________________________
Product Name:____________________________________
Applicant's Name:________________________________
Date Guidance Document Issued:______________________

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

1. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

2. ☐ I have entered into an agreement with one or more other registrants under FIFRA § 3(c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

3. ☐ I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

4. ☐ I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

5. ☐ I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

Dated:____________________

Registrant's authorized
representative:

____
(signature)

____
(typed)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(TO QUALIFY, CERTIFY ALL FOUR ITEMS)

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document dated ____________ to submit data concerning the active ingredient ____:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm	Date of Offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

Dated:____________________ ________________________________

(Signature)

____

(Typed)

cc: A copy of the offer(s) is attached.

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

~~(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)~~

~~[44 FR 27953, May 11, 1979]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five~~

TABLE D
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.

TABLE E

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		

TABLE F-1

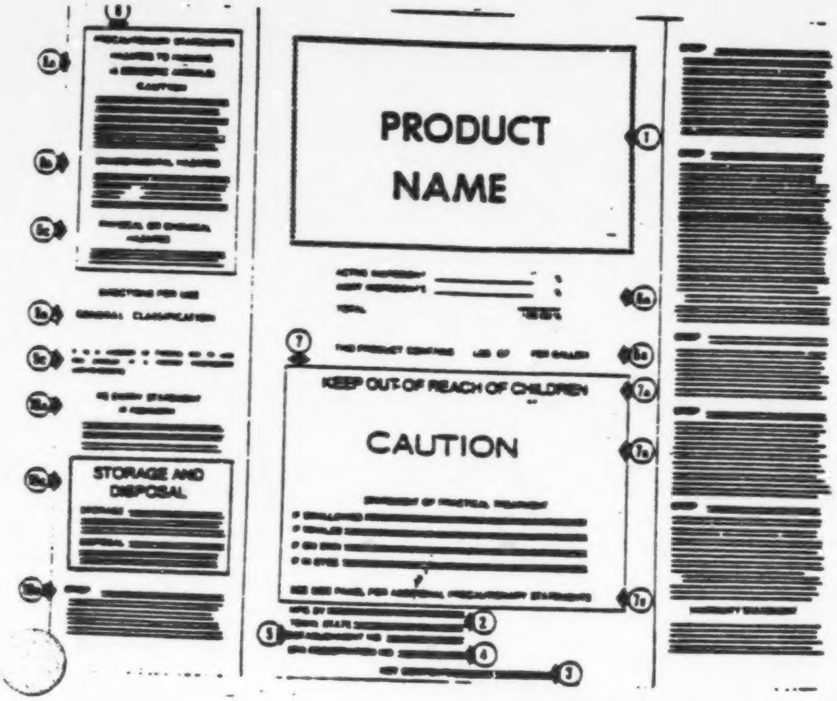
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	

TABLE F-2

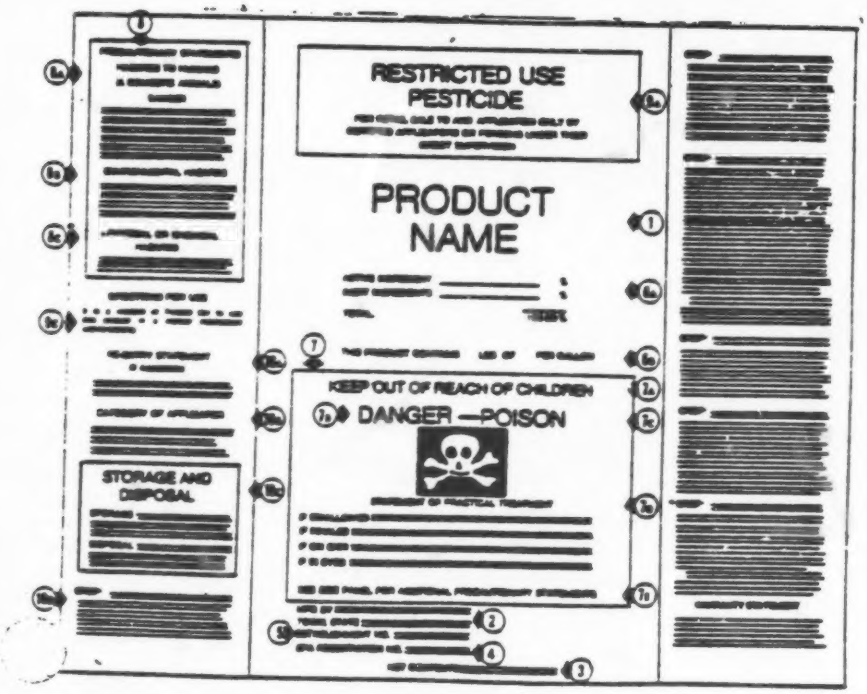
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be grouped together, and preferably blocked. Heading must be same type size as child hazard warning.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

APPENDIX VI-2

SAMPLE LABELS


PRODUCT NAME
KEEP OUT OF REACH OF CHILDREN
CAUTION
STORAGE AND DISPOSAL
1
2
3
4
5
7

General Use Pesticide


RESTRICTED USE PESTICIDE
PRODUCT NAME
KEEP OUT OF REACH OF CHILDREN
DANGER —POISON
STORAGE AND DISPOSAL
1
2
3
4
5
7

Restricted Use Pesticide

Appendix VI-3

PHYSICAL-CHEMICAL HAZARDS

teria	Required Label Statement
Pressurized Containers	
A. Flash point at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

Appendix VI-5

STORAGE INSTRUCTIONS FOR PESTICIDES

ll product labels are required to have appropriate storage nstructions. Specific storage instructions are not prescribed. ach registrant must develop his own storage instructions, onsidering, when applicable, the following factors:

- Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

- Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage temperature, potential for breakage of glass, crushing or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

- Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

- Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

- General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

- General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PROPOSED DISPOSAL STATEMENTS FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. **Household** (all) - Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash collection.

2. **Metal** (all sizes) - Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

3. **Plastic** (all) - Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if approved by State and local authorities.

4. **Glass** (all) - Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.

5. **Fiber drums with liners** - Dispose of liners according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused*, dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.

6. **Paper and plastic bags** - Dispose of bags according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act.

7. **Compressed gas cylinders** - Return empty cylinder for reuse (or similar wording).

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*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

BFC Chemicals Inc.
4311 Lancaster Pike Box 2867
Wilmington, Delaware 19805

SUBJECT: Initiation of Reregistration Process for Manufacturing Use Products and Certain End Use Products Containing DIOXATHION as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this manufacturing use standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development. Together they should provide you with all the information you need to meet the necessary requirements and to allow you to continue your registration(s) in effect.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time.

Additionally, the Guidance Document contains instructions describing what you must do to maintain registration for your product(s). Products not brought into compliance with the Guidance Document will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose for this document.
2. Explains data compensation.
3. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product.
4. Sets out time frames for submission of labeling and for submission of required data.
5. Explains how to revise labeling for manufacturing use products. (As the Guidance Document explains, labeling is not required for end use products at this time.)
6. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this latter. Please note that if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the

Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

George T. LaRocca
Product Manager (15)

Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

ATTACHMENT A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

EPA Reg. No. 45639-16	Delnav Emulsifiable Concentrate
EPA Reg. No. 45639-23	Hercules Delnav Insecticide Toxicant
EPA Reg. No. 45639-48	Clertic Delnav Emulsifiable Liquid

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing Use Product (MUP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).

NONE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

BFC Chemicals Inc.
4311 Lancaster Pike Box 2867
Wilmington, Delaware 19805

SUBJECT: FIFRA Section 3(c)(2)(B) Notice for Manufacturing Use Products and Certain End Use Products Composed of Multiple Active Ingredients That Contain ___DIOXATHION___ As One of the Active Ingredients

Dear Registrant:

This is a notice to you that EPA is requiring registrants of pesticide products containing the subject active ingredient to arrange to submit data to EPA concerning that active ingredient. As this notice explains, within 90 days from your receipt of this letter you must inform EPA either (1) that you are exempt from this requirement or (2) how you will comply with the requirement. If you do not respond, or if you otherwise fail to comply with this notice, EPA may suspend the registration of your products containing that active ingredient. Attachment A is a list of those products. The authority for this notice is Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. Section a(c)(2)(B).

I. Why You Are Receiving This Notice Now

EPA issued now requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978). Many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as were being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [see FIFRA Section 3(g)].

A new review procedure has been developed. Under it, EPA has issued Guidance Documents, each of which discussed a particular pesticide active ingredient. Each Guidance Document summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency currently does not have, compliance with standards of toxicity, composition, labeling, and packaging; and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D). Registrants of manufacturing use products and certain end use products have already received or will receive a copy of this enclosed Guidance Document.

FIFRA requires that a data submission requirement under Section 3(c)(2)(B) must be imposed on the registrants of all products to which the data are pertinent. Some of the data we have required persons subject to the reregistration program to submit are "generic" data which pertain to the safety of the active ingredient of a product, and thus are relevant to all products containing that ingredient (or to all products which contain that ingredient and have certain use patterns or formulation characteristics).

Since these data also may be pertinent to the registrability of your product containning the subject chemical, we are required by Section 3(c)(2)(B) to send you this notice. You are required to comply with this notice, but you are not required at this time to take any steps to reregister your product, e.g., relabel your product.

II. What You Must Do to Comply With This Notice

Within 90 days of your receipt of this Notice you must furnish to EPA a completed copy of the "FIFRA Section 3(c)(2)(B) Summary Sheet" (Attachment B) with appropriate attachments for each of your products. Agency records indicate that you do not quality for the FIFRA Section 3(c)(2)(D) data exemptions, since the source of subject active ingredient is (1) not registered with EPA or/and (2) is not purchased from a firm other than your own. Since you are not exempt, you must determine what data you are required to submit [see paragraph (A) below] and how you will comply with the requirement [see paragraphs (B) through (D) below].

A. What Generic Data Must Be Submitted

You may ascertain which generic data you must submit by consulting the generic data table (Table A in the Guidance Document). That table shows the generic data needed to evaluate the continued registrability of all products containing the subject chemical and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, in the Pesticide Registration Guidelines,*/ or data collected under protocols approved and issued by the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may submit an application to have your registration amended by deleting those uses.

After determining whether you are required to submit data, and if so, which data, choose the appropriate option for each of your affected products.

B. Options Available for Complying with Requirements to Submit Data

You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled "PIFRA Section 3(c)(2)(B) Summary Sheet" (Attachment B) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Program, you must enclose the protocols you will use.

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*/ The Pesticide Registration Guidelines were re-proposed on November 24, 1982 in 47 Federal Register 53192.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must state which of the parties to the agreement will respond to this Notice in the manner specified by paragraph C.2. above. A list of registrants with products containing this active ingredient is included for your information (see Attachment C).

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data." (Attachment D)*/

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii); and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

4. Request that EPA amend your registration by deleting the uses for which the data are needed.

5. Change the source of your active ingredient to one that is (1) registered with EPA and (2) is purchased from a firm that does not have ownership in common with your company. If this selection is made, a revised confidential statement of formula (EPA Form 8570-4) must be submitted which clearly shows from whom the sole source of the subject active is both purchased and registered.

6. Request voluntary cancellation of the registration(s) of your product for which the data are needed.

C. Time Frames for Development and Submission of Required Data

The periods listed in Table A of the Guidance Document are the periods which the Agency will allow for development and submission of the data (measured from the date of receipt of this notice).

D. Procedures for Requesting Changes In Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports from the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Program, you must submit the protocol for Agency review prior to the initiation of the test.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you must submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager named below. The extension request should state the reasons why you conclude that an extension is appropriate. You must strive to meet the deadline for submitting the required data while EPA considers your request.

If, after reviewing this Notice, you do not understand what you must do, or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way.

George LaRocca
Product Manager 15
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

Sincerely yours,

Douglas D. Campt, Director
Registration Division (TS-767)

ATTACHMENT A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

EPA Reg. No. 45639-39	Delnav 8
EPA Reg. No. 45639-41	Hercules Delnav 80 Emulsifiable Solution
EPA Reg. No. 45639-65	Deltic Delnav Emulsifiable Liquid
EPA Reg No. 45639-20	Deltic

ATTACHMENT B

FIFRA §3(c)(2)(B) SUMMARY SHEET

EPA Registration No.:______________________________
Product Name:____________________________________
Applicant's Name__________________________________
Date Guidance Document Issued:________________________

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

1. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use.

2. ☐ I have entered into an agreement with one or more other registrants under FIFRA §3(c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

3. ☐ I enclose a completed "Statement of Willingness to Enter Into An Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

4. ☐ I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

5. ☐ I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

Dated:____________________

Registrant's authorized
representative: ________________________
(Signature)

____
(Typed Name)

ATTACHMENT D

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(TO QUALIFY, CERTIFY ALL FOUR ITEMS)

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document dated ____________ to submit data concerning the active ingredient ____________________________________:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm	Date of Offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

Dated: ____________________ ______________________________
(Signature)

____
(Typed)

cc: A copy of the offer(s) is attached.

ATTACHMENT C

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

Dioxathion

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing Use Product (MUP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).

NONE